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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/005,318	01/09/1998	MICH B. HEIN	310098401C1	2353

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EXAMINER
ROMEO, DAVID S

ART UNIT PAPER NUMBER
1647

DATE MAILED: 12/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/005,318

Applicant(s)

HEIN ET AL.

Examiner

David S Romeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 0703.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The amendment filed July 24, 2003 has been entered. Claims 42-70 are pending. Claims 42-70 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) to the extent that they are drawn to a nonelected species, i.e., a species not encompassed by the species of targeting molecule comprising a J chain encoded by nucleotides 1-213 of SEQ ID NO: 8 covalently linked via a peptide bond to an antigen combining site, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 31. Claims 42-70 are being examined to the extent that they are drawn to the elected species, i.e., a species encompassed by the species of targeting molecule comprising a J chain encoded by nucleotides 1-213 of SEQ ID NO: 8 covalently linked via a peptide bond to an antigen combining site.

Terminal Disclaimer

The terminal disclaimer filed on 07/24/2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent Nos. 6,045,774, 6,251,392, and 6,391,280 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Maintained Formal Matters, Objections, and/or Rejections:

Double Patenting

Claims 42-70 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending

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Application No. 08/782,481. Applicant's request that the examiner defer this issue is acknowledged. However, there are no provisions for deferring an issue.

Claims 42-70 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 6, 7 of U.S. Patent No. 6440419.

Claims 42-70 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/062467. In claim 62 of the present application the biological agent is an enzyme. In claim 6 of the copending application the imaging agent is an enzyme. Applicant's request that the examiner defer this issue is acknowledged. However, there are no provisions for deferring an issue.

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Claim Rejections - 35 USC § 112

Claims 42-70 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Applicant argues that amending the claims to include the CH2 and CH3 domains of IgA or IgM obviates the rejection. Applicant's arguments have been fully considered but they are not persuasive. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing

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identifying characteristics of the genus. In this case, there are no functional or structural limitations to the J-chain portion. A J-chain portion in the absence of structural and/or functional limitations thereto does not provide sufficient distinguishing identifying characteristics of the genus because there is no requirement that the J-chain portion

5 possess the structural and/or functional characteristics required for binding of the targeting molecule to a basolateral factor of an epithelial surface.

Claims 42-70 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a targeting molecule comprising a J chain and the

10 CH2 and CH3 domains of IgA or IgM, does not reasonably provide enablement for a targeting molecule comprising a portion of a J chain and the CH2 and CH3 domains of IgA or IgM. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

15 Applicant argues that amending the claims to include the CH2 and CH3 domains of IgA or IgM obviates the rejection. Applicant's arguments have been fully considered but they are not persuasive. In present case, there are no functional or structural limitations to the J-chain portion. The claims do not require that the J-chain portion possess the structural and/or functional characteristics required for binding of the

20 targeting molecule to a basolateral factor of an epithelial surface. The skilled artisan is left to extensive experimentation wherein molecules comprising a structurally and functionally unlimited J chain portion are randomly made and through trial and error experimentation is left to determine, which bind an unspecified and undefined epithelial

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basolateral factor. Moreover, there is a lack of predictability in the art. Predicting structure, hence function, from primary amino acid sequence data is extremely complex and there doesn't exist an efficient algorithm for predicting the structure of a given protein from its amino acid sequence alone. See Bowie (x32) page 1306, column 1, full paragraph 1, or Ngo (y32) page 433, full paragraph 1, and page 492, full paragraph 2. In view of the breadth of the claims, the limited amount of direction and working examples provided by the inventor, the unpredictability in the art and the quantity of experimentation needed to make or use the invention based on the content of the disclosure, it would require undue experimentation for the skilled artisan to make and/or use the full scope of the claimed invention.

Claims 48, 53, 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 48, 53, 55 are indefinite over the recitation of "comprises amino acid sequence selected from."

Applicant argues that the claims have been amended to obviate this issue. Applicant's arguments have been fully considered but they are not persuasive. It is unclear if an amino acid sequence that is one of the SEQ ID NOs: or an amino acid sequence that is some unspecified portion of one of the SEQ ID NOs: is intended. The metes and bounds are not clearly set forth. It is suggested that the claims recite either "the amino acid sequence of" or "an amino acid sequence selected from the group consisting of."

Claims 58, 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 58, 60 are indefinite over the recitation of "comprises an amino acid sequence from." Applicant argues that the claims have been amended to obviate this issue. Applicant's arguments have been fully considered but they are not persuasive. It is unclear if an amino acid sequence that is one of the SEQ ID NOs: or an amino acid sequence that is some unspecified portion of one of the SEQ ID NOs: is intended. The metes and bounds are not clearly set forth. It is suggested that the claims recite either "the amino acid sequence of" or "an amino acid sequence selected from the group consisting of."

Claim Rejections - 35 USC § 103

Claim 70 is rejected under 35 U.S.C. 103(a) as being unpatentable over Max (AP, cited by Applicants) and Janknecht (uu32).

Applicant argues that the targeting molecule comprises the CH2 and CH3 domains of IgA or IgM. Applicant's arguments have been fully considered but they are not persuasive. The targeting molecule of claim 70 does not comprise any portion of an Ig heavy chain.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that nothing has been cited which demonstrates that a His tag is derived from a cell and the Office action fails to identify any pre-existing property of the cell that is modified by a His tag. Applicant's arguments have been fully considered but they are not persuasive. The present specification at page 7 defines a "biological agent" as any molecule that is synthesized by a cell or ex vivo, can be derived from a cell and/or can be demonstrated to modify the properties of a cell. Janknecht teaches that expression of a His tag within a cell. The His tag is clearly "synthesized by a cell." The nature and extent of the derivation in "derived" is unclear. The His tag is "derived from a cell" in the absence of evidence to the contrary. A cell that lacks a His tag has the property of lacking a His tag.

Applicant argues that there is no motivation to combine. One of ordinary skill in the art would be motivated to combine these teachings because the supply of many eukaryotic proteins which have potential clinical or industrial use is often limited by their low natural availability; gene cloning and expression in can provide a more abundant source of these polypeptides; the advantages of recombinant expression would provide a convenient source of readily purified protein that could be used for structural and/or functional studies. Contrary to Applicant's assertion, the targeting molecule of claim 70 does not comprise any portion of an Ig heavy chain.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include

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knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper.

See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

New Formal Matters, Objections, and/or Rejections:

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Claim Objections

Claim 70 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A targeting molecule that
10 does not comprise an Ig heavy chain or portion thereof (claim 70) fails to further limit a targeting molecule that that comprises an Ig heavy chain portion (claim 42).

Specification

The application is not fully in compliance with the sequence rules, 37 C.F.R. §
15 1.821-1.825. Claims 48, 53, 55, 58, 60 contain a disclosure of SEQ ID NOs: 114-140.
However, these SEQ ID NOs: are not part of the sequence listing.

Correction is required.

Conclusion

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No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHT FAX NUMBERS:

BEFORE FINAL (703) 872-9306

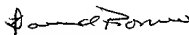
AFTER FINAL (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHT FAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.



DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
DECEMBER 17, 2003